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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,064	PELED ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *201-209,212-219 and 224-243* is/are pending in the application.

4a) Of the above claim(s) *202-208, 215-219, 224-234, 236-237 and 240-243* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *201,209-214,238 and 239* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment to the claims filed on July 18, 2007, has been received and entered. Claims 1-200, 210-211, 220-223 have been canceled, while claims 201 212-214 and 239 have been amended.

Claims 201-209, 212-219, 224-243 are pending in the instant application.

Election/Restrictions

Applicants' election of claims 201, 209-215, 217-231, 235, 238 and 239 (Group I) in the reply filed on October 25 was acknowledged. Applicants have also elected culturing the cells in presence of one copper chelator (claims 201), neonatal umbilical cord cells (claim 209), FLT-3 ligand (claim 212) and granulocyte colony-stimulating factor (claim 214) as election of species for the elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 202-208, 216-218, 232-234, 236-237 and 240-243 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. In addition, Claims 215-219, 224-231 are also withdrawn since these claims are not directed to elected species of culturing cells in presence of at least one copper chelator. Election was made without traverse in the reply filed on October 25, 2006.

Claims 201, 209-214, 238 and 239 are under current examination.

Withdrawn Specification

The objection to the specification is withdrawn in view of amendments to the specification that specifically deletes the embedded hyperlink and/or other form of browser-executable code.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/29/02 and 9/29/06 have been considered by the examiner.

Maintained & New Claim Rejections-Necessitated by amendments - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 201, 209-214, 238 and 239 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of expanding an *ex vivo* population of CD34+ and CD34+CD38- and/or $CD133^+$ hematopoietic stem cell in culture, while at the same time inhibiting differentiation of the said cell ex vivo in culture medium; said method comprising:

(a) providing hematopoietic mononuclear cells that are not enriched prior to culturing , culturing said MNC *ex vivo* in culture under conditions allowing the proliferation and at the same time; said conditions for ex-vivo cell proliferation comprises providing either (i) early acting cytokines selected from the group consisting of stem cell factor, FLT3 ligand, interleukin-1, interleukin-2, interleukin-3, interleukin-6, interleukin-10, interleukin-12, tumor necrosis factor-a and thrombopoietin; and/or (ii) a late acting cytokines selected from the group consisting of granulocyte colony stimulating factor, granulocyte/macrophage colony

stimulating factor, erythropoietin;and (b) culturing said MNC in presence of copper chelator tetraethylenepentamineTEPA;

thereby expanding the population of said hematopoietic stem cell while inhibiting the differentiation of said HSC *ex vivo* in culture medium.

does not reasonably provide enablement for culturing mononuclear cells in presence of any other condition for proliferation or in presence of any other copper chelator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Such a determination is not a simple factual consideration, but is a conclusion reached by weighing at least eight factors as set forth in In re Wands, 858 F.2d at 737, 8 USPQ 1400, 2d at 1404. Such factors are: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the art; (4) The level of one of ordinary skill in the art; (5) The level of predictability in the art; (6) The amount of direction and guidance provided by Applicant; (7) The existence of working examples; and (8) The quantity of experimentation needed to make and/or use the invention.

The office has analyzed the specification in direct accordance to the factors outlines in *In re Wands*. MPEP 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on factors discussed in MPEP 2164.01(a) and the evidence as whole, it is not necessary to discuss each factor in written enablement rejection." These factors will be analyzed, in turn, to demonstrate that one of ordinary skill in the art would have had to perform "undue experimentation" to make and/or use the invention and therefore, applicant's claims are not enabled.

The aspects considered broad are: expanding population of hematopoietic stem cell from hematopoietic mononuclear cell using any copper chelator for

culturing mononuclear cell, using any condition for cell proliferation subsequently limiting to any cytokine or nutrient.

The specification fails to provide an enabling disclosure for the claimed invention because the specification fails to provide sufficient guidance as to how an artisan of skill would have practiced the claimed method of expanding hematopoietic stem cell by culturing MNC under any condition of proliferation in presence of any copper chelator. In the instant case, specification fails to provide any guidance as to how the claimed method would have been practiced in presence of any copper chelator capable of reducing intracellular available copper concentration to any level in said cell. As will be shown below, broad aspects were not enabled for the claimed invention at the time of filing of this application because neither the specification nor the art of record taught sufficient guidance to practice the claimed invention over the full scope. For the purposes to be shown in the state of the prior art, the question of lack of enablement is discussed.

The specification discloses use of various agents in expanding hematopoietic stem cells present in the hematopoietic mononuclear cells fraction of a blood sample, without the use of a prior stem cells enrichment procedure (see page 4, para 5). Pages 25 provide brief description of the figures. The specification teaches *ex-vivo* expanded populations of hematopoietic stem cells, using hematopoietic mononuclear cells that comprise a major fraction of hematopoietic committed cells and a minor fraction of the hematopoietic stem and progenitor cells as a source of stem cells, without prior enrichment of the hematopoietic mononuclear cells for stem cells. The expanded populations of hematopoietic stem cells of the present invention can be used in variety of conditions including hematopoietic cell transplantation, in generation of stem cells suitable for genetic manipulations for cellular gene therapy (see page 26 of the specification). Pages 26-89 of the specification provide a detailed description of the invention, preferred embodiments and provide definition of terms. In addition, it is noted that specification asserts

"hematopoietic mononuclear cells" refers to the entire repertoires of white blood cells present in a blood sample (see page 33, para 2 of the specification, while "hematopoietic stem cells" refers to pluripotent hematopoietic cells that, given the right growth conditions, may develop to any cell lineage present in blood (see page 34, para 2 of the specification). Rest of the specification provides specific examples describing the method of expanding an ex vivo population of hematopoietic stem cell by providing hematopoietic mononuclear cell and culturing in presence of cytokine and copper chelator. These broad disclosures do not demonstrate the information required by the Artisan to reasonably predict that HSC could be expanded *ex vivo* in presence of any copper chelator capable of reducing intracellular available copper concentration in said cells to any level for any duration of time. The specification does not provide specific guidance commensurate with full scope of the claims. Examples 1 of the specification describe that addition of TEPA chelator to non-purified MNC cultures, progressively increased the number of CD34+ cells, CD34+ colony-forming cells and CD34+CD38- cells, over a 12-week period (see example 1, pages 92-93; also see figure 1a, 1b and 2). It is noted that specification teaches that addition of Copper-TEPA chelator (50-100μM) to MNC cultures markedly increases the number of CD34+ cells, and the number of CD34+CD38- cells, after an eight weeks incubation period (see example 2, page 94, Table 1).

The claims 201, 209-214, 238 and 239 embrace a method uses culturing mononuclear cells in presence of at least one copper chelator. The specification has exemplified only culture medium supplement with chelator tetraethylpantamine (TEPA) in presence of right combination of cytokine result in effective expansion of HSC from the MNC. Peled et al (Exp Hematol. 2004; 32(6): 547-55) show that the only low-molecular-weight linear polyamine Cu chelator TEPA at a concentration that moderately reduced cell Cu content (by 20–30%) enabled extensive *ex vivo* expansion of $CD34^+$ cells in cultures supplemented with early-acting cytokines (see page 552). It is emphasized that neither prior nor specification provide any

guidance that instant method could be practiced using any copper chelator. In fact, specification acknowledges that while reducing the present invention to practice, it was surprisingly and unexpectedly found that molecules such as copper chelator repress differentiation and stimulate and prolong proliferation of hematopoietic stem cells (see page 28, lines 26-30). In addition, prior studies have indicated that effect of copper chelator in effecting cellular function is contradictory to one disclosed in the instant application. Percival et al (Am J Clin Nutr. 1998; 67(5 Suppl): 1064S-1068S) while reviewing the role of copper hypothesize that if copper is essential for differentiation, then chelation of copper with TEPA should prevent the cells from differentiating. Percival et al indicated that cells incubated with TEPA and retinoic acid produced the same amount of superoxide anion as did the cells with retinoic acid, indicating that differentiation occurred suggesting more work may be required to study the exact role of genus of copper chelator in expansion of HSC (See page 1066S, col. 2, para. 2). In addition, as amended claims now embrace culturing MNC that are not enriched in presence of at least one copper chelator capable of reducing intracellular available copper concentration. It is emphasized that "capable of" implies a latent property and may not be ever obtained. The specification describes that copper chelate or chelators of the present invention is capable of forming an organometallic complex with a transition metal other than copper including zinc, cobalt, nickel, iron, palladium, platinum, rhodium and ruthenium (See page 54, para. 3 of the specification). In addition, specification also contemplated chelator is a polyamine chelating agent, such as, but not limited to ethylenediamine (page 66, lines 15-20). Thus, the breadth of copper chelator that is capable of reducing intracellular available copper concentration as per the amended claims may be include EDTA, or citrate, that also chelate iron and cationic minerals necessary for cell proliferation. Lovejoy et al. (Blood 100:666-676; 2002) teaches iron chelators, even at concentrations below 0.5 μM can significantly inhibit growth of normal bone marrow stem cells (See Fig. 4, p 669). It is apparent that an

artisan would have to carry out extensive experimentation to make use the invention, and such experimentation would have been undue because of the neither art nor specification provide any guidance commensurate with full scope of the claims as to how the claimed method would have been practiced for expanding HSC using any copper chelator capable of reducing intracellular available copper concentration.

Because of the art, as shown above, does not disclose how hematopoietic stem cells could be expanded *ex vivo* by culturing MNC in presence of copper chelator that is capable of reducing intracellular copper concentration. Artisan could not predict, in the absence of proof to the contrary, that such a method of expanding hematopoietic stem cell would be successful. An artisan would have to carry out extensive experimentation to *ex-vivo* culture and expand while inhibiting differentiation of hematopoietic stem cells, without prior enrichment, and expansion under undefined culture conditions in the presence of any copper chelator, as claimed in the instant application to make use the invention, and such experimentation would have been undue because of the art of expanding HSC ex vivo in presence of any copper chelator capable of reducing intracellular available copper concentration was unpredictable and specification fails to provide any guidance as to how the claimed method would have been practiced commensurate with full scope of the claim.

Response to Arguments

Applicant's arguments with respect to expanding an *ex vivo* population of CD34+ and CD34+ CD38- hematopoietic cells filed on July 18, 2007 have been fully considered but they are moot in view of amendments to the independent claims reciting the enabling scope. However, applicant's arguments filed July 18, 2007 with respect to expanding HSC in presence of at least one copper chelator capable of

reducing intracellular available copper concentration has been fully considered but they are not persuasive. Applicants assert that copper chelators capable of reducing intracellular available copper concentration can effectively inhibit differentiation of stem and progenitor cells in *ex-vivo* culture.

In response, it is noted that as amended claims embrace culturing MNC that in presence of copper chelator capable of reducing intracellular available copper concentration. In the instant case, the phrase, 'capable of' implies the latent property and it is unclear if the property is ever obtained. See also, further analysis under 112, second paragraph, below. The specification describes that copper chelate or chelators of the present invention is capable of forming an organometallic complex with a transition metal other than copper including zinc, cobalt, nickel, iron, palladium, platinum, rhodium and ruthenium (See page 54, para. 3 of the specification). In addition, specification also contemplated chelator is a polyamine chelating agent, such as, but not limited to ethylenediamine (page 66, lines 15-20). Thus, the breadth of copper chelator that is capable of reducing intracellular available copper concentration as per the amended claims may be include EDTA, or citrate, that also chelate iron and cationic minerals necessary for cell proliferation. Lovejoy et al. (Blood 100:666-676; 2002) teaches iron chelators, even at concentrations below 0.5 μM can significantly inhibit growth of normal bone marrow stem cells (See Fig. 4, p 669). Furthermore, Percival et al. (Am. J. Clin. Nutr.; 67(5 Suppl), 1064S-1068S; 1998) while reviewing the role of copper hypothesize that if copper is essential for differentiation, then chelation of copper with TEPA should prevent the cells from differentiating. Percival et al. showed that cells incubated with TEPA and retinoic acid produced the same amount of superoxide anion as did the cells with retinoic acid, indicating that the cells still underwent differentiation, suggesting more work may be required to study the exact role of genus of copper chelator in expansion of HSC (p. 1066S, 2nd column,, 2nd paragraph). Therefore, in view of the art recognized high level of

unpredictability regarding the culture of stem cells and the effects of copper chelation, together with the large quantity of research required to define these unpredictable variables, and the lack of guidance provided in the specification regarding culture and expansion of any mixed population of hematopoietic cells under any condition, in the presence of any copper chelator, it is the position of the examiner that it would require undue experimentation for one of skill in the art to practice the scope of the invention as broadly claimed.

Withdrawn-Claim Rejections - 35 USC § 112

Claims 201, 209-214, 238 and 239 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of amendments to the claims by removing the term "substantially" and reciting the antecedent basis of the limitation.

New- Claim Rejections- Necessitated by the amendments - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 201, 209-214, 238 and 239 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 201 recites a method step, " at leas one copper chelator capable of reducing intracellular available copper concentration in said cell." Claim is unclear because cells are cultured in presence of at least one copper chelator, "capable of reducing intracellular available copper concentration" is a latent property and it is

unclear whether reduction in intracellular available copper concentration actually occurs or that the chelator could potentially reduce intracellular copper concentration upon modification of concentration or under certain conditions. "Capable of" implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained. Claims 209-214, 238 and 239 depend from claim 201 and are included in this rejection.

Withdrawn-Claim Rejections -Necessitated by the amendments - 35 USC § 102

Claims 201, 209-214and 238-239 rejected under 35 U.S.C. 102(a) as being anticipated by Peled et al (Blood, November 16 2002; Vol. 100, No. 11, pp. abstract No. 4076) is withdrawn in view of applicants submission indicting an earlier priority date for instant application.

Maintained-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 201, 209-214, 238 and 239 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandstrom et al (Blood. 1995; 86(3): 958-70, IDS) and Peled et al (WO99/40783, 8/19/1999, IDS).

Prior to instant invention, Sandstrom et al teach a method of ex vivo expansion of peripheral blood mononuclear cells (MNCs), cultured both directly and after selection for CD34+ cells and also compared in static and continuously

perfused cultures containing different cytokines such as interleukin (IL)-3, IL-6, granulocyte colony-stimulating factor (G-CSF), and stem cell factor (SCF). Sandstrom discloses that peripheral blood (PB) and BM MNCs contain many different cell types at various stages of maturation. Sandstrom et al describe the advantage of using CD34+ enriched population but compares the total and progenitor cell production of MNC and CD34+ cell cultures (See page 958, col. 2). It is noted that Sandstrom et al examined how CD34+ selection and/or perfusion affect the performance of PB MNC cultures supplemented with serum and combination of cytokines (see page 959, col. 1). It is noted that Sandstrom et al teach that either cultures inoculated with MNCs or CD34+ cells produced cells that were remarkably similar after 10 days of culture. In addition, Sandstrom et al discloses It is noted that total numbers of cells, CFU-GM, and LTC-IC that could be obtained from perfusion culture of a PB sample cultured as MNCs were greater than those that could be obtained from the same sample selected and cultured as CD34+ cells (see page 964, column 2 and Table 8). However, Sandstrom differed from claimed invention by not comparing the culture of MNC or CD34+ cells in presence of a copper chelator.

Peled et al teach a method of expanding a population of cells including HSC obtained from neonatal umbilical cord blood, while at the same time inhibiting differentiation of the cells. Peled et al teach culturing cells in presence of early and late acting cytokines and, at the same time, for reducing a capacity of the cells in utilizing transition metals such as copper chelator tetraethylenepentamine (TEPA) (See claims 1-17). It is noted that Peled et al also looked the effect of TEPA on the maturation of hematopoietic cells in a two-phase liquid culture procedure wherein peripheral blood mononuclear cells are first incubated in the presence of early growth factors and then in second phase, these factors are replaced by the erythropoietin in presence of copper chelator TEPA (see page 25). The results suggested that TEPA inhibited the erythroid differentiation, but did not significantly affect the proliferation ability of the progenitor cells (see figure 5 and page 25). Peled et al also show that presence of TEPA sustains long-term cultures of HSC in a CD34+ enriched population of cells by inhibiting/delaying cellular differentiation through chelation of copper (see example 2 and 3). Although, Peled et al taught method steps same as one disclosed in the instant claims but differed from claimed invention by disclosing expansion of HSC from a CD34+ enriched population and not from a unselected mononuclear cell population as claimed in the instant invention.

Accordingly, in view of the teachings of Sandstrom and Peled, it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the method of taught by Sandstrom by culturing MNC directly and after selection for CD34+ cells in presence of a copper chelator such as TEPA with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification, as it was art recognized

goal to *ex-vivo* expand cells that include HSC and more differentiated progenitor cells in order to optimize short-term recovery and long-term restoration of hematopoiesis. Sandstrom emphasized the importance of expansion of all progenitor cells, especially those committed to the neutrophilic and megakaryocytic lineages, concomitant with expansion of stem cells in order to decrease the extent and duration of cytopenias after transplantation (see page 967, col. 2 bridging to page 968, col. 1). In addition, Peled had already disclosed that CD34+ cell cultures with early-acting cytokines and TEPA, it is possible to maintain long term cultures (LTC) without the support of stroma (see example 2). Although Peled et al did not use mononuclear cell, he used peripheral blood mononuclear cells in a two-phase liquid culture to show the potential of TEPA in inhibiting erythroid differentiation (supra). Sandstrom sought to examine how CD34+selection affect the performance of MNC cultures supplemented with different combination of cytokines. Therefore, given that copper chelator such as TEPA was available for use to expand CD34+ enriched population of HSC as per the teachings of Peled, itt would have been obvious to an artisan to use copper chelator such as TEPA in the unselected or CD34+ selected cells taught by Sandstrom. The skilled artisan would be motivated to modify the method of Sandstrom in order to compare the expansion potential and to determine the role of TEPA on expansion of cells that are committed to the neutrophilic and megakaryocytic lineages concomitant with expansion of stem cells to reduce the extent and duration of cytopenias after transplantation. In addition, such a direct *ex vivo* expansion from MNC would have also resulted in fewer steps to quickly obtain HSC for various transplantation purposes. It is noted that obtaining MNC from different source was routine practice in the art for expanding HSC and the skilled Artisan would have motivated to optimize method to obtain MNC from different source for expansion of HSC (see MPEP 2144.04).

One who would practiced the invention would have had reasonable expectation of success because Sandstrom had already described a method of *ex vivo* expansion of peripheral blood mononuclear cells (MNCs), cultured both directly and after selection for CD34+ cells in presence of cytokine. Peled had already described use of copper chelator such as TEPA could be used for inhibiting differentiation of MNC or expanding CD34+ cells. Thus, it would have only required routine experimentation to modify the method disclosed by Sandstrom to also culture cell in presence of TEPA as required by instant invention.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed July 18, 2007 have been fully considered but they are not persuasive. Applicants argue that the Peled reference does not qualify as prior art to the instant invention as discussed in 102 rejection; and therefore, this rejection should be withdrawn.

In response, it is noted that Applicant errs in suggesting that Peled does not qualify as prior art particularly since reference used in this rejection (Peled et al, WO99/40783, 8/19/1999, IDS) is different from one cited for 102 rejection. It is noted that Peled et al (WO99/40783, 8/19/1999) qualify for instant rejection. In absence of any substaintail argument or rebuttal, instant rejection is maintained for the reasons of record.

Conclusion

No Claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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